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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,416	03/15/2004	Paul C. Mioduski	62815.00002	1961

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EXAMINER

GIBSON, ROY DEAN

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 09/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/801,416	Applicant(s) MIODUSKI ET AL.	
	Examiner Roy D. Gibson	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/20/04, 2/24/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamaguchi (5,433,740).

As to claim 1-4, Yamaguchi discloses a method of operating a system for heating the body of a patient comprising:

measuring a temperature that is within an allowable range of operation for the system;

determining whether to continue operation of the system based on a parameter related to the measured temperature; wherein the parameter comprises the measured temperature; wherein the parameter comprises a temperature

difference between the measured temperature and another measured temperature; and wherein the parameter comprises a rate of change of temperature (col. 1, line 55-col. 2, line 39 and col. 8, line 50-col. 11, line 19).

As to claim 5-8 and 21-22, Yamaguchi discloses a device for heating the body of a patient comprising:

a heat source (heater 41) for providing heat for the hyperthermia treatment';

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a temperature sensor (A-D) for measuring temperature from the providing of heat; a processor that determines whether to continue the hyperthermia treatment based on a parameter related to a measured temperature that is within an allowable range of operation for the device; wherein the parameter comprises the measured temperature, a temperature difference between the measured temperature and another measured temperature or the rate of change of the temperature (col. 3, line 45-col. 5, line 58, col. 8, line 50-col. line 37).

Further to claims 21-22, the recitation is directed only to the intended use of the device rather than to its structural elements and is not, therefore, given any patentable weight.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8 and 17-22 rejected under 35 U.S.C. 102(e) as being anticipated by Ellingboe (6,818,012).

As to claim 1-4, Ellingboe discloses a method of operating a system for heating the body of a patient comprising:

measuring a temperature that is within an allowable range of operation for the system;
determining whether to continue operation of the system based on a parameter related to the measured temperature; wherein the parameter comprises the measured temperature; wherein the parameter comprises a temperature

difference between the measured temperature and another measured temperature; and wherein the parameter comprises a rate of change of temperature (col. 2, line 19-col. 4, line 40 and col. 5, line 4-col. 10, line 65).

As to claim 5-8 and 21-22, Ellingboe discloses a device for heating the body of a patient comprising:

a heat source (heater 62) for providing heat for the hyperthermia treatment';
a temperature sensor (70 and 72) for measuring temperature from the providing of heat; a processor (PID controller) that determines whether to continue the hyperthermia treatment based on a parameter related to a measured temperature that is within an allowable range of operation for the device; wherein the parameter comprises the measured temperature, a temperature difference between the measured temperature and another measured temperature or the rate of change of the temperature (col. 5, line 5-col. 8, line 60 and col. 13, lines 44-col. 14, line 67).

Further to claims 21-22, the recitation is directed only to the intended use of the device rather than to its structural elements and is not, therefore, given any patentable weight.

As to claims 17- 20, Ellingboe discloses a system and a method of operating the treatment system comprising:
determining when the system has provided a desired temperature (measures the actual temperature of the input liquid to the pad and the external temperature of the patient);
evaluating a duration of the treatment (a criteria pertaining to a thermal dose); and
terminating the treatment when the time or temperature are not delivered at the

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predetermined set-point values (Figure 4 condition 370 and col. 9, line 59-col. 6, line 65).

Further to claims 19 and 20, Ellingboe discloses a method and device or system as detailed above and also monitoring the temperature of the circulating fluid (Figure 4, step 400) and sending a user alert when the fluid temperature is not maintained (step 420) and col. 9, line 59-col. 6, line 65).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellingboe. Ellingboe discloses a method of operating a treatment system comprising:

- performing a plurality of tests to determine whether the hyperthermia treatment system is operating properly (Figure 4); and
- terminating operation of the hyperthermia treatment system in response to failure of any test of a predefined set of the tests (steps 300-390). But, Ellingboe fails to disclose preventing further operation of the hyperthermia treatment system until the hyperthermia treatment system is reset for further operation at a specified facility such as the manufacturer of the system equipment. However, the examiner maintains that one of ordinary skill in the art would know the typical quality assurance procedure

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established in the medical industry for the preliminary testing of all incoming equipment including performing the specified tests to the satisfaction of the QA engineers and if failures occur, returning the equipment to the manufacturer to correct or reset the parameters to insure proper operation of the equipment. These tests to verify proper operation would be performed either inside or outside of a housing or both as required and local resets attempted as directed (including providing a special code to the system) by the established QA procedure provided by the manufacturer.

Conclusion


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Marchosky et al. (4,719,919) disclose an implantable hyperthermia device and system with computer control of the treatment temperature.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy D. Gibson whose telephone number is 571-272-4767. The examiner can normally be reached on M-F, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Roy D. Gibson
Primary Examiner
Art Unit 3739

September 28, 2005